



Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference Number: 97-0816

JUL -7 1998

Johan Van Hoof, Ph.D.
SmithKline Beecham Biologicals
89, rue de l'Institut
1330 Rixensart
Belgium

Dear Dr. Van Hoof:

The Supplement to your Product License Application for Hepatitis B Vaccine, (Recombinant) to include the use of Hepatitis B Vaccine, (Recombinant) in individuals with chronic hepatitis C infection, has been approved.

This information will be included in your Product License Application file.

Sincerely yours,

A handwritten signature in cursive script, reading "M. Carolyn Hardegree", is written over the typed name.

M. Carolyn Hardegree, M.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

cc: Ms. Debra Hackett